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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,084	12/05/2005	Christine Vauthier	1721-89	9469

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,084	VAUTHIER ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

It appears that the wording of Claims 10-12 in the instant application fail to follow the standards or format for U.S. applications, reciting "Use of" rather than "A method for". Furthermore, Claim 11 recites dependency on the composition of Claim 10; however, Claim 10 is a method claim. It is suggested that the claim language be corrected so as to place the application in better form for examination.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, drawn to a compound comprising a hemoprotein associated with a sequenced block copolymer comprising a hydrophilic segment that is an oligosaccharide or a polysaccharide linked to at least one hydrophobic segment of Formula I and a method of using said compound as a human or animal blood substitute.

Group II, claim 11, drawn to a method of using a compound as an adjuvant for anti-tumor compositions or other anti-tumor means.

Group III, claim 12, drawn to a method of using a compound comprising a hemoprotein associated with a sequenced block copolymer comprising a hydrophilic segment that is an oligosaccharide or a polysaccharide linked to at least one hydrophobic segment of Formula I as an agent for de-polluting gases.

Group IV, claim 13, drawn to a pharmaceutical composition that contains an unknown composition in the form of nanoparticles.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:
"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:
"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)."

The special technical feature of Group I is a method step of using a composition comprising a hemoprotein as a blood substitute; whereas, the special technical feature of Group III is the method step of using a composition comprising a hemoprotein as an agent for de-polluting gases. The special technical features of Groups II and IV are an unknown composition for use as an anti-tumor adjuvant or as a radiosensitizing agent and an unknown composition formulated for pharmaceutical purposes, respectively. The "open" claim language used in Claim 1 establishes an enormous genus of structurally diverse compositions such that instantly claimed compound for use as a radiosensitizing agent, for example, is indeterminate.

3. **Should Applicant elect Group I, a species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of "X", "Y", "R", "R-prime" and "R-double prime" radicals. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species for each of "X", "Y", "R", "R-prime" and "R-double prime" radicals, specifically:

i) wherein "X" is an H, alkyl, CN or CONHR radical, as recited in Claim 1

ii) wherein "Y" is a COOR', CONHR", C6H5, a phenyl or an ester radical, as recited in Claims 1 and 7,

iii) wherein "R" is an H, a linear C1 to C20 alkyl group, a branched C1 to C20 alkyl group, a linear C1 to C20 alkoxy group, a branched C1 to C20 alkoxy group, an amino acid radical, a mono-hydroxylated acid radical, a polyhydroxylated acid radical, a C5 to C12 aryl radical, or a C5 to C12 heteroaryl radical, as recited in Claim 1,

iv) wherein "R-prime" is an H, a linear C1 to C20 alkyl group, a branched C1 to C20 alkyl group, a linear C1 to C20 alkoxy group, a branched C1 to C20 alkoxy group, an amino acid radical, a mono-hydroxylated acid radical, a polyhydroxylated acid radical, a C5 to C12 aryl radical, or a C5 to C12 heteroaryl radical, as recited in Claim 1,

v) wherein "R-double prime" is an H, a linear C1 to C20 alkyl group, a branched C1 to C20 alkyl group, a linear C1 to C20 alkoxy group, a branched C1 to C20 alkoxy group, an amino acid radical, a mono-hydroxylated acid radical, a polyhydroxylated acid radical, a C5 to C12 aryl radical, or a C5 to C12 heteroaryl radical, as recited in Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple radicals that are structurally distinct. The numerous variations in the number, position and type of carbon atoms result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a hydrogen to have the same chemical properties as a branched C16 alkoxy group. Each of the radical species moiety confers a unique, non-obvious, distinctly different

technical feature onto the hydrophobic segment that will directly impact functional property of the block copolymer. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited "X", "Y", "R", "R-prime" and "R-double prime" radicals imposes an exceptional burden on the Office. As the technical feature, the hydrophobic segment, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claim 1, and claims dependent therefrom correspond to all the species listed above.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Should Applicant elect Group I and one species for each "X", "Y", "R", "R-prime" and "R-double prime" radical from above, a further species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of hemoproteins. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species for each hemoprotein, wherein the hemoprotein is (see Claim 2), specifically:

i) a normal hemoprotein,

ii) a modified hemoprotein, or

iii) a hemoprotein analogue in which the iron is substituted with another metal.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple hemoproteins that are structurally distinct. The numerous variations in the mutations, polymerizations, number, position and type of modifications result in a vast genus of structurally unrelated hemoprotein molecules that are not obvious variations of each other because one skilled in the art does not expect a hemoprotein in which the iron is substituted with cobalt to have the same biological effect as a blood substitute as a hemoprotein containing iron. Given the breadth of the claimed, unrelated structures, a search for all possible hemoprotein species imposes an exceptional burden on the Office. As the technical feature, that is a hemoprotein, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named hemoprotein species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claim 1, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 1.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Should Applicant elect Group I and one species for each "X", "Y", "R", "R-prime" and "R-double prime" radical and a hemoprotein species from above, a further species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of hydrophilic segments. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single hydrophilic segment species (see Claim 6) wherein the hydrophilic segment is a saccharide that is, specifically:

i) a natural oligosaccharide,

ii) a natural polysaccharide,

iii) a synthetic oligosaccharide that is not modified

iv) a synthetic oligosaccharide that is modified,

v) a synthetic polysaccharide that is not modified,

vi) a synthetic polysaccharide that is modified,

vii) dextran,

viii) a sulfated dextran, or

ix) heparin.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple hydrophilic saccharides that are structurally distinct. The numerous variations in the number, position and type of modifications and saccharide units result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a natural oligosaccharide to have the same biological and chemical properties as a synthetic polysaccharide that is modified. Given the breadth of the claimed, unrelated structures, a search for all possible species of hydrophilic

saccharides imposes an exceptional burden on the Office. As the technical feature, a saccharide, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named hydrophilic saccharide species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claim 1, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 1.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER